

**Claims.**

1. A process for making a medicinal vial comprising:
  - 5 (1) providing a vial mould having an openable cavity therein defining the shape of a medicinal vial having a mouth opening,
  - (2) moulding a vial in the vial mould cavity using a mouldable medicinally acceptable polymer,
  - (3) opening the vial mould to expose the so-formed vial,
  - 10 (4) removing the so-formed vial body from the vial mould,
  - (5) automatically inserting a sterile puncturable closure into the mouth opening of the so-formed vial body using automatic mechanical handling means, and wherein at least steps (3) to (5) are performed under sterile conditions.
- 15 2. A process according to claim 1 comprising:
  - (1) providing a vial mould having an openable cavity therein defining the shape of a medicinal vial having a mouth opening,
  - (2) moulding a vial in the vial mould cavity using a mouldable medicinally acceptable polymer,
  - 20 (3) opening the vial mould to expose the so-formed vial,
  - (4) removing the so-formed vial from the vial mould,
  - (6) providing a closure mould having an openable cavity therein defining the shape of a puncturable closure for the mouth opening of the medicinal vial,
  - (7) moulding a puncturable closure in the closure mould cavity using a mouldable medicinally acceptable elastomeric polymer,
  - 25 (8) opening the closure mould to expose the so-formed puncturable closure,
  - (9) removing the so-formed puncturable closure from the closure mould,
  - (5) automatically inserting the so-formed puncturable closure into the mouth opening of the so-formed vial,
- 30 and wherein at least steps (3), (4), (5), (8) and (9) are performed under sterile conditions.

3. A process according to claim 1 or 2 wherein the vial and closures are either or both made by an injection moulding process in which initially solid polymer is fluidised by heat and pressure typically by a helical screw, and is then forced under pressure into the mould cavity.

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4. A process according to claim 1, 2 or 3 wherein the vial mould cavity is shaped to make a vial having an internally cylindrical tubular shape, with an open end defining a mouth opening, and an opposite closed end, with a flange externally around the mouth opening.

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5. A process according to any one of the preceding claims wherein the vial mould cavity is shaped to make a vial having a closed end with an engagement part suitable for engagement with automatic mechanical handling means.

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6. A process according to any one of the preceding claims wherein a cyclo-olefin thermoplastic polymer is used to make the vial.

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7. A process according to any one of the preceding claims wherein the closure mould is constructed to make multiples of the numbers of vials made by the vial mould.

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8. A process according to any one of the preceding claims wherein steps (4), (5) and (9) are performed by automatic handling means able to releasably engage with the vial and closure formed in the respective vial and closure moulds, to remove the formed vial and closure from their moulds, and to bring a vial and closure together to engage a vial with a closure.

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9. A process according to claim 8 wherein the automatic handling means is configured to releasably engage with plural vials and closures, to remove plural vials and closures from their moulds, and to bring plural vials and closures together to engage plural vials with plural closures simultaneously.

10. A process according to claim 8 or 9 wherein the automatic handling means engages with the exterior of the closed end of the vial, and engages with a part of the closure which will not be in contact with the interior of the vial when the closure is in place.

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11. A process according to claim 8, 9 or 10 wherein the automatic handling means releasably engages with the vial or closure by a suction means that draws the vial or closure into contact with engaging means of the automatic handling means.

10 12. A process according to any one of claims 8 to 11 wherein the handling means engaged with a closure introduces the closure into a vial in step (5) whilst the vial is also engaged by handling means.

15 13. A process according to claim 12 wherein the handling means releases the vial so that the engaged vial and closure is retained by the handling means engaged with the closure.

20 14. A process according to any one of the preceding claims wherein after the assembly of vial and closure in step (5) the assembly is transferred automatically to a further processing station at which one or more further process is performed on the assembly.

15. Apparatus for performing a process according to any one of the preceding claims comprising:

25 (A) a vial mould having an openable cavity therein defining the shape of a medicinal vial having a mouth opening, and in which a vial may be moulded using a mouldable medicinally acceptable polymer, and which may be opened to expose a vial moulded therein,

30 (B) a closure mould having an openable cavity therein defining the shape of a closure for a medicinal vial when moulded in the first mould, and in which a closure may be moulded using a mouldable medicinally acceptable polymer, and which may be opened to expose a closure moulded therein,

(C) automatic mechanical handling means adapted to insert a puncturable closure made in the closure mould into the mouth opening of a vial made in the vial mould,

(D) means to provide a sterile environment in relation to (A), (B) and (C)  
5 such that said vial and closure moulds may be opened, a respective vial and closure may be removed from the respective vial and closure moulds, and the closure inserted into a vial, in the sterile environment.

16. Apparatus according to claim 15 wherein the vial and closure moulds are  
10 both or either injection moulds in which initially solid polymer is fluidised by heat and pressure typically by a helical screw, and is then forced under pressure into the mould cavity.

17. Apparatus according to claim 15 or 16 wherein the vial mould cavity is  
15 shaped to make a vial having a closed end with an engagement part suitable for engagement with automatic mechanical handling means.

18. Apparatus according to claim 15, 16 or 17 wherein the closure mould is  
constructed to make multiples of the numbers of vials made by the vial mould.  
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19. Apparatus according to any one of claims 15 to 18 provided with automatic handling means able to releasably engage with the vial and closure formed in the respective vial and closure moulds, to remove the formed vial and closure from their moulds, and to bring a vial and closure together to engage a vial with a  
25 closure, to perform steps (4), (5) and (9).

20. Apparatus according to claim 19 wherein the automatic handling means is configured to releasably engage with plural vials and closures, to remove plural vials and closures from their moulds, and to bring plural vials and closures together  
30 to engage plural vials with plural closures simultaneously.

21. Apparatus according to claim 19 or 20 wherein the automatic handling means is configured to engage with the exterior of the closed end of the vial, and to engage with a part of the closure which will not be in contact with the interior of the vial when the closure is in place.

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22. Apparatus according to claim 19, 20 or 21 wherein the automatic handling means is configured to releasably engage with the vial or closure by a suction means that draws the vial or closure into contact with engaging means of the automatic handling means.

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23. Apparatus according to any one of claims 19 to 22 wherein the handling means is configured to introduce a closure closure engaged by the handling means into a vial in step (5) whilst the vial is also engaged by handling means.

15 23. Apparatus according to claim 23 wherein the handling means is configured to release the vial so that the engaged vial and closure is retained by the handling means engaged with the closure.

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